This estimate is based on the number and frequency of submissions received in the past and on discussions between FDA staff and respondents during routine communications. The actual time required for each submission will vary in relation to the size of the company and the breadth of its marketing activities.

Dated: December 12, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–32426 Filed 12–20–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95D–0115]

Compliance Policy Guides Manual; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of an updated bound edition of ''FDA Compliance Policy Guides'' (CPG manual). The CPG manual explains FDA's policy on regulatory issues related to FDA laws and regulations. The CPG manual is intended to provide guidance to FDA field inspection and compliance staffs.

ADDRESSES: The CPG manual may be ordered from National Technical Information Service (NTIS), U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161. Orders must reference NTIS order number PB96–915499 for each copy of the document. Payment may be made by check, money order, charge card (American Express, Visa, or MasterCard), or billing arrangements made with NTIS. Charge card orders must include the charge card account number and expiration date. For telephone orders or further information on placing an order, call NTIS at 703–487–4650. The CPG manual is available for public examination in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Barbara A. Rodgers, Office of Regulatory Affairs (HFC–230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0417.

SUPPLEMENTARY INFORMATION: FDA is issuing the updated bound edition of the CPG manual to provide information both on new and revised CPG's. CPG's that are new or revised with this printing are identified in the index at the end of the manual.

The statements made in the CPG manual are not intended to create or confer any rights, privileges, or benefits on or for any private person or to bind FDA, but they are intended merely for internal FDA guidance.

Dated: December 12, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–32423 Filed 12–20–96; 8:45 am]

BILLING CODE 4160–01–F

Establishment Prescription Drug User Fee Revenues and Rates Fiscal Year 1997

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is establishing user fee revenues and rates for Fiscal Year (FY) 1997. The Prescription Drug User Fee Act of 1992 (the PDUFA) authorizes FDA to collect user fees for certain applications for approval of drug and biological products, on establishments where the products are made, and on such marketed products. Fees for applications, establishments, and products for FY 1993 were established by the PDUFA. Fees for future years are to be determined by FDA using criteria delineated in the statute.

FOR FURTHER INFORMATION CONTACT: Michael E. Roosevelt, Office of Financial Management (HFA–120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4872.

SUPPLEMENTARY INFORMATION:

I. Background

The PDUFA (Pub. L. 102–571) establishes three different kinds of user fees. Fees are assessed on: (1) Certain types of applications and supplements for approval of drug and biologic products, (2) certain establishments where such products are made, and (3) certain marketed products (21 U.S.C. 379h(a)). When certain conditions are met, FDA may waive or reduce fees (21 U.S.C. 379h(d)). Under the PDUFA, one-third of the total user fee revenue for each FY must come from each of the three types of fees.

For FY 1993, the total revenues to be derived from fees and the fee rates for each of the categories were established in the PDUFA (21 U.S.C. 379h(b)(1)). For FY 1994 through 1997, however, the PDUFA establishes only target total fee revenues and fees. For these years, FDA is authorized to increase the total fee revenues and to establish new fee rates for each of the three categories so that the revised total fee revenues are realized (21 U.S.C. 379h(c)).

This notice establishes total fee rates for FY 1997. These fees are retroactive to October 1, 1996, and will remain in effect through September 30, 1997. For fees already paid on applications and supplements submitted on or after October 1, 1996, FDA will bill/refund applicants for the difference between fees paid and fees due under the new fee schedules. For applications and supplements submitted after December 31, 1996, the new fee schedule should be used. Invoices for establishment and product fees for FY 1997 will be issued in December 1996, using the new fee schedules.

II. Revenue Increase and Fee Adjustment Process

The PDUFA provides that total fee revenues for each FY, as set out in the original fee schedule (see 21 U.S.C. 379h(b)(1)), shall be increased by notice in the Federal Register. The increase must reflect the greater of : (1) The total percentage increase that occurred during the FY in the Consumer Price Index (the CPI) (all items; U.S. city average), or (2) the total percentage pay increase for that FY for Federal employees, as adjusted for any locality-based payment applicable to employees stationed in the District of Columbia (see 21 U.S.C. 379h(c)(1)). The PDUFA also provides that within 60 days after the end of each FY, FDA shall adjust the user fee rates in each of the three categories of fees (application, establishment, and product) to achieve the revised total fee revenues. The new individual user fees must be adjusted in a manner that maintains the proportions established in the original fee schedules, so that approximately one-third of the revenues will come each from applications, establishments, and product fees (21 U.S.C. 379h(c)(2)).

III. Total Fee Revenue Adjustment

For FY 1996, the total percentage increase in the CPI was 3.00 percent, whereas the increase in applicable Federal salaries for FY 1997 is 3.33 percent. Thus, for computing the total fee revenues for FY 1997, the percentage is 3.33. The new adjusted total fee revenue is computed by applying the increase as a percentage (103.33 percent) to the FY 1997 target fee revenue amount from the PDUFA schedule ($84 million). The FY 1997